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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,444	02/17/2004	Peter M. Bonutti	782-A03-023	2789
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PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER SZPIRA, JULIE ANN	
			ART UNIT	PAPER NUMBER
			3731	
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			12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,444

Applicant(s)

BONUTTI ET AL.

Examiner

JULIE A. SZPIRA

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18-24 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 7/9/2008. Claims 1-8, 18-24 and 49-52 are pending and an action on the merits is as follows. Claims 25-48 were previously cancelled and claims 9-17 have been withdrawn from consideration in this action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-8, 19 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Egan (US 6,174,324)**.

Regarding claim 1, Merritt discloses a device that is capable of acting as a suture holder (cord lock, 10) capable of securing a suture relative to a body tissue comprising a first (male body, 14) section including a first surface (54) and an extension member (projection, 66) extending from that surface, and a second (female body, 12)

section including a second surface (34) opposing the first surface and being configured for receiving the extension member (recess, 35), the first and second section being bondable together with the application of an energy source (ultrasonic welding; column 4, lines 35-36), but fails to disclose the first and second surfaces being configured to abut the suture.

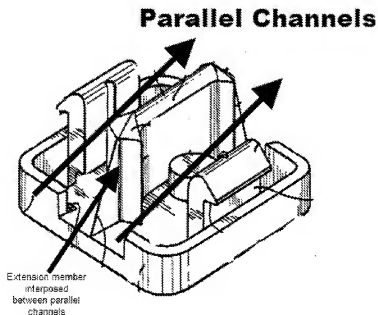
However, Egan et al. teaches the first and second surfaces being configured to abut the suture (Figure 12; column 5, lines 3-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the first and second surfaces to abut the suture to apply the necessary tension to the suture to retain the suture strands (column 3, lines 51-55).

Regarding claim 2, Merritt discloses the suture (cord) interposed between the first and second sections (column 3, lines 15-18).

Regarding claim 3, Merritt discloses the first and second section bonded (snap-locked) together to secure the suture (column 4, lines 13-20).

Regarding claim 4, Merritt discloses the first section including a pair of parallel channels (Figure 4, see below).



Regarding claim 5, Merritt discloses the extension member (66) interposed between the pair of parallel channels (Figure 4, see above).

Regarding claim 6, Merritt discloses the second section including a channel (recess, 35) configured for receiving the extension member (column 3, lines 56-59).

Regarding claim 7, Merritt discloses the suture (cord) including a first (19) and second (21) end, one each positioned within the parallel channels (column 3, lines 62-64; Figure 1).

Regarding claim 8, Merritt discloses the suture interposed between the first and second sections when the extension member is positioned within the channel (column 4, lines 16-20).

Regarding claim 18, Merritt discloses the invention substantially as claimed above, but fails to disclose at least one of the first or second contact surfaces being textured.

However, Egan et al. teaches the internal surfaces of the device having internal texturing

It would have been obvious to one having ordinary skill in the art at the time the invention was made to texture the first and second sections to enhance the retention and tension of the suture strands within the device (column 4, lines 47-51).

Regarding claim 19, Merritt discloses the first and second sections interconnected by a system of pins and recesses (column 4, lines 11-16).

Regarding claim 24, Merritt discloses the energy source being ultrasonic energy (welding) (column 4, lines 33-36).

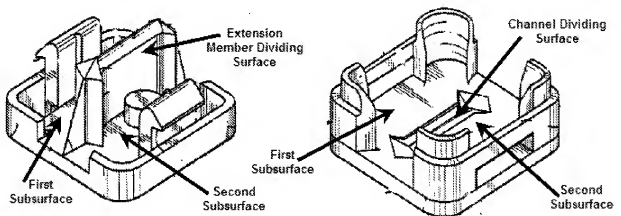
Regarding claim 49, Merritt discloses the invention substantially as claimed above, but fails to disclose the first and second surface configured to sandwich the suture.

However, Egan et al. teaches the first and second surfaces configured to sandwich the suture (Figure 12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the first and second surfaces to sandwich the suture to apply the necessary tension to the suture to retain the suture strands (column 3, lines 51-55).

Regarding claim 50, Merritt discloses the first second has two channels (76) formed therein, said channels being disposed opposingly about and immediately adjacent to said extension member and the second section is configured to seat within the channels of the first section (Figure 3).

Regarding claim 51, Merritt discloses said extension member divides said first surface into a first first-surface subsurface and a second first-surface subsurface, a channel divides said second surface into a first second-surface subsurface and a second second-surface subsurface (See Figure Below), said first first-surface subsurface is configured to align with said first second-surface subsurface when said first section is bonded to said second section; and said second first-surface subsurface is configured to align with said second second-surface subsurface when said first section is bonded to said second section (Figure 3)



Regarding claim 52, Merritt discloses the invention substantially as claimed above, but fails to disclose a suture being disposed between at least one of said first first-surface subspace and said first second-surface subspace and said second first-surface subspace and said second second-surface subspace.

However, Egan et al. teaches a suture sandwiched between a first first-surface subspace and said first second-surface subspace and a second first-surface subspace and said second second-surface subspace (Figure 12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to place a suture between the subsurfaces to apply the necessary tension to the suture to retain the suture strands (column 3, lines 51-55).

4. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Egan (US 6,174,324)**, further in view of **Hart (US 5,630,824)**.

Regarding claim 20, Merritt in view of Egan discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of a biodegradable material.

However, Hart teaches a suture retainer (attachment device) made of a biodegradable polymer (column 4, lines 50-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a biodegradable material so the device can dissolve after the wound which the suture is attached to heals (column 4, lines 52-65).

5. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Egan (US 6,174,324)**, further in view of **Tokushige et al. (US 5,866,634)**

Regarding claim 21, Merritt in view of Egan discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of heat shrink material.

However, Tokushige et al. teaches a biodegradable shrink material that has superior strength, flexibility, and the ability to shrink at lower temperatures (column 1, lines 39-42; column 4, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a heat shrink material because it would allow the suture retainer to shrink around the suture (container) with minimal warping (column 3, lines 24-26).

6. **Claims 22 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Egan (US 6,174,324)**, further in view of **Bartlett (US 5,879,372)**,

Regarding claims 22 and 23, Merritt in view of Egan discloses the invention substantially as claimed above, but fails to disclose the suture retainer including viable cells or pharmaceutical agents.

However, Bartlett teaches the suture retainer (anchor) including viable cells (bone tissue) and pharmaceutical agent (hydroxyapatite) (column 4, lines 34-36 and 46-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include viable cells and a pharmaceutical agent to strengthen the area in which the device is placed (column 4, lines 24-26).

Response to Arguments

7. Applicant's arguments with respect to claims 1-8, 19 and 24 have been considered but are moot in view of the new ground(s) of rejection.

8. In response to applicant's argument that Merritt nonanalogous art, and therefore could not be combined to make the suture anchor disclosed in claims 20 and 21, it has been held that a prior art reference must either be in the field of applicant's endeavor or,

if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the device disclosed by Merritt is structurally similar to many suture anchors well known in the art. The application of a cord retainer as a suture retainer is well within the knowledge of one having ordinary skill in the art. The decision to make the device disclosed by Merritt from a variety of different materials suitable for a suture anchor, such as a biodegradable material or a heat shrink material would have been obvious to one having ordinary skill in the art.

The applicant also argues that an elastic cord behaves different than a suture, and cites the difference in size between a cord and a suture. However, a change in size is not pertinent to the matter of patentability and therefore is not a limitation to be considered. Further, applicant has not claimed a specific suture size at any point in the claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Julie A Szpira/
Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731